



7020-02

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-956]

### Certain Recombinant Factor VIII Products

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the presiding administrative law judge (ALJ) has issued a final initial determination on May 27, 2016, and a recommended determination on remedy and bonding on June 3, 2016.

The ALJ found no violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337). Should the Commission, however, find a violation of Section 337, the ALJ recommends that the Commission issue a limited exclusion order that excludes from importation into the United States certain recombinant factor VIII products manufactured by processes that infringe certain claims of U.S. Patent Nos. 6,100,061 and 8,084,252. The respondents are Novo Nordisk A/S of Bagsvaerd, Denmark, and Novo Nordisk Inc. of Plainsboro, N.J. Upon a finding of a violation, the ALJ further recommends that cease and desist orders issue to respondents and be directed to respondents' domestic inventories.

This notice is soliciting public interest comments only from the public. Parties are to file public interest submissions pursuant to 19 C.F.R. § 210.50(a)(4) within 30 days from service of the recommended determination.

**FOR FURTHER INFORMATION, CONTACT:** Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, (202) 205-3427. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>, and will be available for inspection during official

business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, (202) 205-2000.

General information concerning the Commission may also be obtained at <http://www.usitc.gov>.

The public record for this investigation may be viewed on EDIS at <http://edis.usitc.gov>. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal at (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. § 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. § 1337(f)(1).

Therefore, the Commission is interested in further developing the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five pages, inclusive of attachments, concerning the public interest in light of the ALJ's recommended determination on remedy and bonding issued in this investigation on June 3, 2016. Comments should address whether the issuance of a limited exclusion order and cease and desist order would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) explain how the articles potentially subject to the recommended orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;
- (iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;
- (iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended exclusion order and/or a cease and desist order within a commercially reasonable time; and
- (v) explain how the limited exclusion order and cease and desist order would impact consumers in the United States.

Written submissions must be filed no later than by close of business on June 29, 2016.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number (Inv. No. 337-TA-956) in a prominent place on the cover page, the first page, or both. *See Handbook for Electronic Filing Procedures*, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the

Secretary at (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R. § 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and of sections 201.10, 210.46, and 210.50 of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 201.10, 210.46, 210.50).

By order of the Commission.

Issued: June 6, 2016

Lisa R. Barton

Secretary to the Commission

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